

DEPARTMENT OF VETERANS AFFAIRS

8320-01

38 CFR Part 17

RIN 2900-AO78

Hospital Care and Medical Services for Camp Lejeune Veterans

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends Department of Veterans Affairs (VA) regulations in order to implement a statutory mandate that VA provide health care to certain veterans who served at Camp Lejeune, North Carolina, for at least 30 days during the period beginning on January 1, 1957, and ending on December 31, 1987. The law requires VA to furnish hospital care and medical services for these veterans for certain illnesses and conditions that may be attributed to exposure to toxins in the water system at Camp Lejeune. This rule does not implement the statutory provision requiring VA to provide health care to these veterans' family members; regulations applicable to such family members will be promulgated through a separate notice.

DATES: <u>Effective Date</u>: This rule is effective [<u>insert date of publication in the FEDERAL REGISTER</u>].

FOR FURTHER INFORMATION CONTACT: Terry Walters, Deputy Chief Consultant, Post-Deployment Health, Office of Public Health (10P3A), Veterans Health Administration, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461-1017 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: On September 11, 2013, VA published a notice of proposed rulemaking setting forth proposed regulations to provide hospital care and medical services to certain veterans who served at Camp Lejeune for at least 30 days from January 1, 1957, to December 31, 1987. 78 FR 55671-55675, Sept. 11, 2013. Interested persons were invited to submit comments on or before October 11, 2013. We received a total of 65 comments. All of the issues raised by the commenters that opposed at least one portion of the rule can be grouped together by similar topic, and we have organized our discussion of the comments accordingly. Based on the rationale set forth in the proposed rule and in this document, VA is adopting the proposed rule as a final rule with one change to 38 CFR 17.400(d)(2)(A).

<u>Limitations on retroactive copayments</u>

In paragraph § 17.400(d)(2)(A) of the proposed rule, we had stated that in order to receive retroactive reimbursement for care provided by VA for a condition or illness that was made copayment exempt, veterans must request Camp Lejeune status no later than September 11, 2015. We explained that we selected that date because it was two years after publication of the proposed rule. We received numerous comments on this provision.

First, commenters misunderstood the effect of § 17.400(d)(2)(A). To be clear, it is not a deadline to enroll in VA as a Camp Lejeune veteran. Rather, as we explained in the proposed rule, § 17.400(d)(2) establishes that VA would retroactively reimburse certain copayments paid by Camp Lejeune veterans for VA-provided health care. There is no deadline for a veteran to enroll in VA and be recognized as a Camp Lejeune veteran.

Commenters were also concerned about the deadline for retroactive copayments. For example, one individual noted that a veteran could be treated for a period of time without being diagnosed with one of the 15 conditions, and stated that in such a case the veteran's copayments should be returned to the veteran. Another commenter suggested that VA apply a deadline for retroactive copayment only after VA notifies the affected veteran of his or her eligibility for Camp Lejeune veteran status and the procedures to apply for retroactive reimbursement.

We note that as soon as the law became effective, VA began an aggressive effort to notify veterans of the Camp Lejeune veteran status. VA does not hold or maintain the records of all individuals who served at Camp Lejeune, and has instead engaged in comprehensive outreach to all veterans. In addition, new enrollees in the VA healthcare system are now required to answer on the enrollment form, VA form 10-10EZ, whether they served at Camp Lejeune for the requisite time periods. VA has conducted, and will continue to conduct for at least the next two years, aggressive outreach to veterans through the Marine Corp registry and the Agency for Toxic Substances and Disease Registry (ATSDR) Community Action Panel, and will provide education to VA environmental health providers. VA has directly notified Veteran Service Organizations on the benefit that VA is providing to veterans. VA has used both print and digital methods to reach the largest possible number of veterans. Finally, VA clinicians are being trained to identify the 15 illnesses or conditions and ask whether veterans diagnosed as having one of them served at Camp Lejeune.

Having a deadline after which VA will not accept retroactive claims for copayment reimbursement is necessary to ensure program integrity and reduce potential

administrative burdens associated with retroactive reviews of old claims. It is also consistent with other retroactive payment authorities in part 17 of title 38, Code of Federal Regulations. See 38 CFR 17.129 and 17.1004. We do, however, accept the commenters' suggestions that more time is needed for veterans to learn about this program. We therefore adjust the deadline for submission of a request for Camp Lejeune status to obtain eligibility for retroactive reimbursement from September 11, 2015, to September 24, 2016. This will align the two-year deadline with the date that this rule takes effect, rather than the date that it was proposed.

<u>Issues concerning enrollment procedures</u>

We received several comments about the enrollment process. Some commenters asked specific questions about how the regulation would be applied to their particular cases, or identified themselves as Camp Lejeune veterans and requested benefits. Whenever possible, based on identifying information provided in the comment, we have contacted these individuals privately to assist them. It is inappropriate to address individuals' claims with specificity in this notice; however, several commenters were concerned that the enrollment process would be burdensome, or that VA would require veterans to fill out forms or otherwise take actions that, in practice, VA does not require. To address these concerns, we assure the public that enrollment as a Camp Lejeune veteran will be as seamless and simple as possible. Veterans who identify themselves as Camp Lejeune veterans on VA Form 10-10EZ and whose status is confirmed will not need to re-enroll for VA care or take any further action in order to be copayment-exempt for future care related to their Camp Lejeune illness. Veterans also will generally not need to take any specific actions, once

their status is verified, to receive retroactive reimbursement for copayments paid before their Camp Lejeune status was established (as long as the care was provided on or after August 6, 2012, the date that the legislation authorized VA to begin providing Camp Lejeune benefits). VA will pay retroactive copayments in accordance with paragraph (d)(2) of the regulation without requiring further action by such veterans. Only in extraordinary situations – for example, if it is not immediately apparent that the claimant is a veteran – will VA require veterans to take additional action by providing more information or evidence related to their claims.

One commenter was concerned that veterans will not remember the exact dates that they resided at Camp Lejeune. The commenter was also concerned, generally, that older veterans have difficulty filling out forms.

We understand that some veterans may have difficulty completing VA's application for enrollment, VA Form 10-10EZ, which is available online at https://www.1010ez.med.va.gov/. VA offers resources at the local level in VA Medical Centers to assist veterans in filling out our forms. In addition, we operate a help line (1-877-222-VETS(8387)). Moreover, we note that veterans who are already enrolled need only identify themselves as Camp Lejeune veterans at their local facility or on the help line—or state that they believe they may qualify as a Camp Lejeune veteran—and VA will take appropriate action, without requiring that the veteran fill out a new form or remembering the specific dates they resided at Camp Lejeune. Finally, VA recently revised the VA Form 10-10EZ in order to reduce the burden on veterans. VA will continue to provide veterans with assistance to complete applications, and provide Camp Lejeune veterans with specific guidance and help. However, we do not make

any changes based on the above comments.

Concerns over clinical identification of illnesses or conditions

Many commenters were concerned by § 17.400(c), which states that VA will assume that one of the 15 illnesses or conditions are considered attributable to the veteran's active duty in the Armed Forces unless VA clinically determines under its clinical practice guidelines that the illness or condition is not attributable to the veteran's service. One commenter suggested that VA include a "preponderance of the evidence" standard of proof for determining whether a Camp Lejeune veteran's illness or condition is attributable to a cause other than service at Camp Lejeune. Other commenters suggested that VA remove § 17.400(c) entirely because, they assert, it is impossible to determine the cause of a specific illness or condition. We are not making any changes to the final rule based on these comments because the comments misconstrue the effect of the law and regulation.

Under 38 U.S.C. 1710(e)(1)(F), VA is required to provide hospital care and medical services to a veteran who served at Camp Lejeune who has one of the 15 identified illnesses or conditions. VA does not, and cannot, require veterans to produce affirmative evidence of a connection between their illness or condition and exposure to contaminated water at Camp Lejeune. The only limitation on this requirement is that, under 38 U.S.C. 1710(e)(2)(B), VA is barred from providing such care to a veteran based solely on the veteran's status as a Camp Lejeune veteran if the veteran's illness or condition is found, in accordance with guidelines issued by the Under Secretary for Health, to have resulted from a cause other than exposure at Camp Lejeune. In other words, the burden is on VA to clinically determine that, in a particular veteran's case, his

or her illness or condition resulted from something other than service at Camp Lejeune.

Thus, VA practice will not be to require veterans to make an affirmative showing of a connection unless VA determines that an illness or condition is not connected to service at Camp Lejeune.

Moreover, it is not VA's intent, nor has it been our practice, to attempt to disqualify Camp Lejeune veterans from receiving copayment-free care for a listed condition or illness. We acknowledge that given current science, it may be difficult in many situations to determine the cause of a veteran's illness or condition. In these cases, VA will give the benefit of the doubt to the veteran.

For example, one commenter stated that lung cancer, one of the 15 listed illnesses or conditions, could be erroneously attributed to cigarette smoking rather than service at Camp Lejeune. Medical science cannot definitively distinguish clinically whether the origin of an individual's lung cancer is the result of service at Camp Lejeune or cigarette smoking. Therefore, VA would not be able to rule out the clinical possibility that the veteran's lung cancer was caused by service at Camp Lejeune, and such a veteran would receive his or her cancer treatments without being required to make a copayment. This would be true even if cigarette smoking were medically more likely than not the cause of the veteran's lung cancer.

Some commenters questioned whether the proposed rule would cover secondary illnesses or conditions that arise from, or lead to the development of, one of the 15 listed illnesses or conditions. Once VA enrolls a Camp Lejeune veteran as a Priority Group 6 veteran, that individual receives comprehensive VA care; however, pursuant to 38 U.S.C. 1710(e)(1)(F), VA may only waive copayments for hospital care and medical

services provided for one of the 15 illnesses or conditions. Therefore, VA will determine clinically whether a separate condition or illness was caused by or resulted from one of the 15 illnesses or conditions. VA will also determine clinically whether any prior treatment was provided for one of the 15 illnesses or conditions that was undiagnosed at the time that the hospital care or medical services were provided. If such a clinical nexus exists, then VA would waive or reimburse the copayment. If VA clinically determines that the illness or condition is not related to one of the 15 illnesses or conditions, then VA will assess a copayment. Similarly, VA cannot reimburse a copayment if VA clinically determines that the previously provided hospital care or medical services were not for one of the 15 illnesses or conditions. This is consistent with the limited mandate to provide care in section 1710(e)(1)(F) and VA's provision of hospital care and medical services for other Priority Group 6 veterans. See 38 CFR 17.108(d).

One commenter provided an example of breast cancer, which is one of the 15 illnesses covered by the statute that metastasizes to the patient's brain. VA clinicians evaluate the unique needs of each patient, and will do so for Camp Lejeune veterans as well. We will use this same approach for determining the clinical progression of an illness or condition in each Camp Lejeune veteran. In this example, if a VA clinician determines that a Priority Group 6 Camp Lejeune veteran's breast cancer (one of the 15 listed illnesses) may have spread to his or her brain, and VA waives copayment for the breast cancer due to the connection to service at Camp Lejeune, then VA would also waive copayments for treatment of the brain cancer. If the VA clinician affirmatively identifies a clinical origin of the brain cancer other than the breast cancer, then VA will

assess copayments for the treatment of the brain cancer.

One commenter suggested that VA implement baseline screenings for all Camp Lejeune veterans. Once VA enrolls veterans in the healthcare system, regardless of their Priority Group level, veterans and their clinicians together determine what is appropriate for each individual's clinical needs. Screenings for one or more of the 15 illnesses or conditions may often be clinically indicated and medically appropriate. In such cases, VA would consider such screenings to be related hospital care or medical services, and Camp Lejeune veterans will not be charged a copayment.

Some commenters stated that Camp Lejeune veterans who have been diagnosed with at least one of the 15 illnesses or conditions should be able to continue to see their private physicians in order to ensure continuity of care. Some also suggested that VA reimburse veterans, either prospectively or retroactively, for care obtained from private physicians. We noted in the proposed rule that 38 U.S.C. 1710 only authorizes VA to provide direct hospital care and medical services to certain veterans. 78 FR 55672, Sept. 11, 2013. Section 1710 does not authorize VA to provide payment or reimbursement for care that VA did not provide to the veteran. Referral for non-VA medical care once enrolled is for preauthorized care. VA will authorize non-VA care for Camp Lejeune veterans in the same manner that VA authorizes such care for all Priority Group 6 veterans. In general, VA is a direct care provider, but may preauthorize non-VA care for certain veterans based on a variety of circumstances, such as the urgency of an individual's medical condition, the relative distance of the travel involved, or the nature of the treatment required, in accordance with our authority in 38 USC 1703 and 8153 Subject to the provisions of § 17.400(d)(2), VA will reimburse Camp Lejeune veterans for copayments made for preauthorized non-VA hospital care and medical services that VA furnished on or after August 6, 2012. Commenters also inquired about reimbursement for costs incurred by Camp Lejeune veterans for hospital care and medical services that veterans obtained from non-VA providers prior to acquiring Camp Lejeune veteran status. Although, as noted above, VA does preauthorize non-VA hospital care and medical services when clinically appropriate, this law does not authorize VA to pay for hospital care and medical services that have already been provided to the veteran from a non-VA provider.

Similarly, one commenter stated that he is a Camp Lejeune veteran who obtains his care locally, and that by doing so, rather than travelling to the nearest VA facility, he was saving VA "thousands of dollars." He requested reimbursing veterans for local care when the veteran lives more than one hour away from the closest VA hospital that can provide care. VA understands that there are instances where geography is a vital factor in determining the best course of treatment or care. As noted above, VA preauthorizes non-VA care based on a variety of circumstances, including geographic location, and will make the same determinations for Camp Lejeune veterans.

In addition, veterans enrolled in Priority Group 6, which includes Camp Lejeune veterans, may be eligible for travel benefits associated with their care in accordance with 38 CFR part 70—although eligibility as a Camp Lejeune veteran does not independently establish eligibility for travel benefits. We do not make any changes based on this comment.

A commenter requested that VA add "and symptoms arising therefrom prior to diagnosis" to § 17.400(c) in order to ensure that VA exempts veterans from copayments

for hospital care and medical services provided for symptoms that existed before the appropriate diagnosis was made. We note that when issues of copayments are connected to clinical determinations, VA defers to the expertise of the clinical provider. VA conducts the same review process for veterans receiving treatment in connection to exposure to Agent Orange. First, the veteran requests a review of his copayments by calling the VA call center at 1-877-222-VETS(8387). The call center will then refer the request to VA Utilization nurses who manually review the claim and the veteran's medical records. The nurses also contact the providers. If the veteran's provider determines that the hospital care and medical service provided prior to the diagnosis of one of the 15 conditions or illnesses were attributable to the veteran's service at Camp Lejeune, then the provider will update the veteran's progress notes and VA will manually process a refund of the copayment. Camp Lejeune veterans will be able to request the same review of copayments made for hospital care and medical services furnished by VA prior to the diagnosis of one of the 15 illnesses or conditions. We therefore make no changes to the rule based on the above comments.

One commenter asked whether VA would require veterans to repay copayments waived or reimbursed for care for one of the 15 illnesses or conditions if VA later determines that the veteran's illness or condition resulted from a cause other than his or her service at Camp Lejeune. VA would assess a copayment for such hospital care or medical services, but we note that those instances would be rare. See 38 CFR 17.102(a) (authorizing VA to recoup payment when care is provided in error). VA would attempt to make the clinical determination about the origin of an illness or condition at the time that the veteran either enrolls, or if enrolled, the time that the veteran notifies

VA of his or her service at Camp Lejeune during the relevant time periods. Any veteran who self-identified as a Camp Lejeune veteran and received care from VA for one of the 15 illnesses or conditions, may be subject to copayments for care provided prior to the publication of this final rule if VA determines that the illness or condition resulted from a cause other than service at Camp Lejeune.

A commenter suggested that VA recruit doctors who specialize in one or more of the 15 listed illnesses or conditions, and that those doctors be in the U.S. Military, or be veterans. We note that VA currently employs clinicians who specialize in each of the 15 illnesses or conditions. Though VA proudly employs a great number of veterans, it is not our view that one's status as a veteran or member of the armed forces has any bearing on an individual's ability to serve as a VA clinician. VA seeks to recruit well-qualified clinicians and will continue to do so utilizing existing hiring practices.

<u>Appeals</u>

One commenter suggested that the rule "should include provisions that provide for notice of a denial, the provision of the research forming the basis for the denial, and the opportunity to challenge the denial before a judicial body" and provide the "ability of Camp Lejeune veterans to challenge the clinical practice guidelines and the denial of medical assistance."

Veterans are given the same appeal rights for Camp Lejeune benefits as for other benefits administered by VA. Along with the written explanation for the denial of benefits, the veteran receives a form explaining the appeals process (VA Form 4107VHA for VHA decisions). Part 20 of title 38, CFR, gives the Board of Veterans' Appeals jurisdiction over questions of law and fact that affect the provision of VA

benefits. The Board's jurisdiction also extends to questions of eligibility for health care benefits administered by the Veterans Health Administration, which would include eligibility as a Camp Lejeune Veteran. See 38 CFR 20.101(b). The clinical practice guidelines provide factors for clinicians to consider when determining whether an illness or condition is attributable to a cause other than the veteran's residence at Camp Lejeune. The guidelines explain such clinical indications, evolve over time, and encourage clinicians to consider the veteran's full history in order to make the best possible clinical determination. The clinical practice guidelines will serve as a resource to VA clinicians and will not require that VA clinicians take specific actions. Therefore, we do not make any changes based on the above comment.

Comments suggesting expanding VA's authority

A number of commenters raised specific concerns with the statute authorizing the provision of hospital care and medical services.

Many commenters suggested other conditions or illnesses that should be covered. Other commenters stated that the dates of eligible service at Camp Lejeune, January 1, 1957, to December 31, 1987, should be expanded to cover veterans who served at Camp Lejeune before or after such dates. Regardless of the merit of these comments, VA is without legal authority to provide benefits other than those authorized by statute. We do not make any changes based on these comments.

Some commenters suggested that veterans be compensated in connection to their service at Camp Lejeune. Several suggested that they had been unable to conceive a child, and believed that this inability was directly due to exposure at Camp Lejeune, and asked to be compensated accordingly. VA cannot expand our authority

through regulation beyond what Congress authorizes us to provide in law. Section 1710(e)(1)(F) of title 38, U.S.C., authorizes VA only to provide health care; it is not a compensation program. We lack authority to provide compensation under this law; however, if the commenter believes that they have a service-connected disability due to their exposure at Camp Lejeune, they should file a disability compensation claim with the Veterans Benefits Administration.

One commenter suggested that VA furnish hospital care and medical services for individuals who served at Camp Lejeune while on active duty for training. We are legally barred from doing so because 38 U.S.C. 1710(e)(1)(F) requires VA to furnish hospital care and medical services to Camp Lejeune veterans who "served on active duty." Active duty is defined, as a matter of law, in 38 U.S.C. 101(21)(A), as full-time duty in the Armed Forces, other than active duty for training.

Some commenters raised issues of the validity of the studies relied on by

Congress in enacting this law. VA cannot expand benefits beyond those granted by

statute, even if the commenters believe that science does not support certain limitations
in the law. Therefore, we do not make any changes based on the above comments.

Comments related to VA claims backlog

Commenters requested that VA improve its claims backlog for veteran benefits. We note that this issue is outside the scope of this rulemaking and VA will therefore not respond to those comments here.

Comments related to family members

A number of commenters raised issues related to VA's furnishing of hospital care and medical services to the family members of Camp Lejeune veterans. As we noted in

the proposed rule, VA will publish a separate rulemaking concerning the family members of Camp Lejeune veterans. Such comments are outside the scope of this rulemaking and no changes will be made to this rule based on those comments.

Effect of Rulemaking

Title 38 of the Code of Federal Regulations, as revised by this rulemaking, represents VA's implementation of its legal authority on this subject. Other than future amendments to this regulation or governing statutes, no contrary guidance or procedures are authorized. All existing or subsequent VA guidance must be read to conform with this rulemaking if possible or, if not possible, such guidance is superseded by this rulemaking.

Administrative Procedure Act

In accordance with 5 U.S.C. 553(d)(3), the Secretary of Veterans Affairs finds good cause to issue this final rule with an immediate effective date. This rule is necessary to provide clarity regarding VA's duty to provide health care to veterans who may have been exposed to toxic substances due to their service at Camp Lejeune. Section 102 of Public Law 112-154 requires VA to provide hospital care and medical services to Camp Lejeune veterans for the listed conditions and illnesses as of August 6, 2012. Many of the 15 listed conditions or illnesses are life-threatening and require immediate medical care. VA is capable of treating Camp Lejeune veterans for such illnesses or conditions immediately, which may lead to improved health outcomes for

many veterans. However, this rule provides VA with the necessary framework to immediately implement this statutory requirement.

This rule clearly defines how VA proposes to identify and integrate Camp Lejeune veterans into its enrollment system so VA can provide necessary health care to these veterans. For example, Public Law 112-154 requires VA to provide hospital care and medical services to "a veteran who served on active duty in the Armed Forces at Camp Lejeune, North Carolina, for not fewer than 30 days during the period beginning on January 1, 1957, and ending on December 31, 1987." The legislation, however, does not define the scope of who should be considered a Camp Lejeune veteran. This rule at § 17.400(b) in the definition for "Camp Lejeune veteran" explains that a veteran served at Camp Lejeune if he or she was stationed at Camp Lejeune, or traveled to Camp Lejeune as part of his or her professional duties. The regulation also explains that the 30-day minimum service requirement may be "consecutive or nonconsecutive" days. Without this regulation, VA would not be able to clearly identify all the veterans who should be provided the necessary health care as a result of their service at Camp Lejeune. Because of this final rule, VA will be able to identify those individuals who should be considered Camp Lejeune veterans and conduct outreach to the identified class of veterans. Although we expect most Camp Lejeune veterans to seek VA medical care for treatment of their illness or condition regardless of this rule, there may be some veterans who may go without treatment if they are not identified as a Camp Lejeune veteran, and their illness or condition does not result in eligibility for enrollment. Because many of the 15 listed conditions or illnesses are life-threatening and require

immediate medical care, this rule with an immediate effective date is necessary to allow VA to provide medical care to all individuals identified as Camp Lejeune veterans.

Furthermore, under the provisions of this rule, VA will be able to reimburse veterans for copayments that certain veterans may have already paid for illnesses or conditions identified in this rule. An immediate effective date will allow VA to reimburse copayments to alleviate this financial hardship for some of these veterans.

For these reasons, the Secretary has concluded that ordinary effective-date procedures would be impracticable and contrary to the public interest and is accordingly issuing this final rule with immediate effective date.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. This final rule has no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

This final rule contains no new provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). However, we note that veterans would apply for hospital care and medical services as a Camp Lejeune veteran under § 17.400 by completing VA Form 10-10EZ, "Application for

Health Benefits," which is required under 38 CFR 17.36(d) for all hospital care and medical services. The Office of Management and Budget (OMB) approved the collection of information for VA Form 10-10EZ and assigned OMB control number 2900-0091. As discussed in a separate notice (78 FR 39832, July 2, 2013), we requested approval from OMB to amend this form to include a specific checkbox for individuals to identify themselves as meeting the requirements of being a Camp Lejeune veteran. OMB approved the amended collection. This particular amendment to the form will have no appreciable effect on the reporting burden for the revised VA Form 10-10EZ. We also do not anticipate a significant increase in the total number of applications filed because most Camp Lejeune veterans likely would have applied for VA medical care for treatment of their illness or condition regardless of this rule.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-12. This final rule will directly affect only individuals and will not affect any small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final flexibility analysis requirements of 5 U.S.C. 603 and 604.

Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic,

environmental, public health, and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a "significant regulatory action," requiring review by OMB as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined, and it has been determined to be a significant regulatory action under Executive Order 12866. VA's impact analysis can be found as a supporting document at http://www.regulations.gov, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's Web site at http://www1.va.gov/orpm/, by following the link for "VA Regulations Published."

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this rule are 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; and 64.022, Veterans Home Based Primary Care.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Jose D. Riojas, Chief of Staff, approved this document on June 18, 2014, for publication.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day

care, Dental health, Drug abuse, Health care, Health facilities, Health professions,

Health records, Homeless, Medical devices, Medical research, Mental health programs,

Nursing homes, Veterans.

Dated: September 18, 2014.

William F. Russo,

Acting Director,

Office of Regulation Policy & Management,

Office of the General Counsel.

U.S. Department of Veterans Affairs.

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For the reasons set forth in the supplementary information of this rulemaking, the Department of Veterans Affairs amends 38 CFR part 17 as follows:

PART 17 -- MEDICAL

1. The authority citation for part 17 continues to read as follows:

AUTHORITY: 38 U.S.C. 501, and as noted in specific sections.

§ 17.36 [AMENDED]

2. Amend § 17.36(b)(6) by removing "38 U.S.C. 1710(e);" and adding, in its place, "38 U.S.C. 1710(e); Camp Lejeune veterans pursuant to § 17.400;".

§ 17.108 [AMENDED]

3. Amend § 17.108(e)(2) by removing "or post-Gulf War combat-exposed veterans;" and adding in its place "post-Gulf War combat-exposed veterans, or Camp Lejeune veterans pursuant to § 17.400;".

§ 17.110 [AMENDED]

4. Amend § 17.110(c)(4) by removing "or post-Persian Gulf War combatexposed veterans." and adding in its place "post-Persian Gulf War combat-exposed veterans, or Camp Lejeune veterans pursuant to § 17.400.".

§ 17.111 [AMENDED]

- 5. Amend § 17.111(f)(5) by removing "or post-Persian Gulf War combat-exposed veterans." and adding in its place "post-Persian Gulf War combat-exposed veterans, or Camp Lejeune veterans pursuant to § 17.400.".
- 6. Add an undesignated center heading and § 17.400 to read as follows:

 Hospital Care and Medical Services for Camp Lejeune Veterans and Families

 § 17.400 Hospital care and medical services for Camp Lejeune veterans.
- (a) <u>General</u>. In accordance with this section, VA will provide hospital care and medical services to Camp Lejeune veterans. Camp Lejeune veterans will be enrolled pursuant to § 17.36(b)(6).
 - (b) <u>Definitions</u>. For the purposes of this section:

<u>Camp Lejeune</u> means any area within the borders of the U.S. Marine Corps Base Camp Lejeune or Marine Corps Air Station New River, North Carolina.

Camp Lejeune veteran means any veteran who served at Camp Lejeune on active duty, as defined in 38 U.S.C. 101(21), in the Armed Forces for at least 30 (consecutive or nonconsecutive) days during the period beginning on January 1, 1957, and ending on December 31, 1987. A veteran served at Camp Lejeune if he or she was stationed at Camp Lejeune, or traveled to Camp Lejeune as part of his or her professional duties.

(c) <u>Limitations</u>. For a Camp Lejeune veteran, VA will assume that illnesses or conditions listed in paragraph (d)(1)(i) through (xv) of this section are attributable to the veteran's active duty in the Armed Forces unless it is clinically determined, under VA

clinical practice guidelines, that such an illness or condition is not attributable to the veteran's service.

- (d) <u>Copayments</u>. (1) <u>Exemption</u>. Camp Lejeune veterans are not subject to copayment requirements for hospital care and medical services provided on or after August 6, 2012, for the following illnesses and conditions:
 - (i) Esophageal cancer;
 - (ii) Lung cancer;
 - (iii) Breast cancer;
 - (iv) Bladder cancer;
 - (v) Kidney cancer;
 - (vi) Leukemia;
 - (vii) Multiple myeloma;
 - (viii) Myleodysplasic syndromes;
 - (ix) Renal toxicity;
 - (x) Hepatic steatosis;
 - (xi) Female infertility;
 - (xii) Miscarriage;
 - (xiii) Scleroderma;
 - (xiv) Neurobehavioral effects; and
 - (xv) Non-Hodgkin's Lymphoma.
- (2) <u>Retroactive Exemption</u>. VA will reimburse Camp Lejeune veterans for any copayments paid to VA for hospital care and medical services provided for one of the illnesses or conditions listed in paragraph (d)(1) of this section, if the following are true:

(i) The veteran requested Camp Lejeune veteran status no later than September

24, 2016; and

(ii) VA provided the hospital care or medical services to the Camp Lejeune

veteran on or after August 6, 2012.

(Authority: 38 U.S.C. 1710)

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